

The Restriction Requirement also requires the election of a singled disclosed species pursuant to 35 U.S.C. § 121. The Restriction Requirement requires the selection of one specific solubilized composition and to specify 1) whether the composition is an aqueous solution or oil emulsion and 2) to name the specific solubilizing agent used. In response to the requirement for election, Applicants provisionally elect: 1) an aqueous solution and 2) cyclodextrin, with traverse. Applicants respectfully reserve the right to prosecute the non-elected claims and species in a continuation or divisional application and also respectfully reserve the right to traverse the Examiner's requirement of a restriction/election in a future response to the U.S. Patent and Trademark Office. Furthermore, upon allowance of a generic claim, Applicants understand that they may be entitled to claim additional non-elected species which fully embrace the allowed generic claim.

Applicants traverse the Examiner's restriction requirement. Contrary to the Examiner's statement that Inventions I and II are related as product and process, claims 31-44, 145-152 are in fact composition claims that Applicant believes should have been included in the Group I set of claims. In the present Restriction Requirements, claims 31-44, 145-152 are classified in Group II "drawn to methods of treating cancer". For at least the reasons stated, Applicants respectfully request that the Restriction Requirement be revised to include claims 31-44, 145-152 in the Group I beta-lapachone composition claims.

Furthermore, Applicants traverse the Examiner's requirement for election of a single specific solubilizing agent. Applicants request modification of the present election requirement under 37 C.F.R. §1.143. The M.P.E.P. states:

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, **the examiner must examine all claims on the merits, even though they are**

directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention.** *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). **Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.**

Applicants submit that election of the aqueous solution alone is satisfactory and allows the Examiner to perform a competent search. Additionally, Applicants submit that the aqueous solubilizing agents function in a similar manner and that retaining all the aqueous solubilizing carrier molecules, such as those recited in the Markush claims throughout the application (e.g. claims 4, 13, 23, 38) would not unduly burden the Examiner's search. For at least these reasons stated, Applicants request modification of the election requirement to include all aqueous solubilizing agents as set forth in the present claims.

Additionally, Applicants request modification of the Restriction Requirement with regard to the grouping of the claims in conjunction with the election of species requirement. The present Restriction Requirement groups the claims into Groups I and II. As stated *supra*, Applicants believe that certain composition claims are incorrectly grouped in Group II and request modification to place these claims in Group I. Applicants note, however, that there is some ambiguity in the requirement for election in which the Examiner has requested election of "an aqueous solution or oil emulsion". Applicants note that the present claims recite the compositions in aqueous solution (i.e. claims 1-6, 11-13, 21-23, 35, 180-182, 196) compositions in oil solution (7-8, 16-17, 35, 41, 42, 190 and claims in emulsion (i.e. claims 10, 20, 29, 138-

144, 145-152, 188, 197). Applicant's respectfully assert that the present election requirement does not take into consideration these three (3) types of solubilizing carrier molecules.

Applicants note that without modification, the present election requirement will effectively eliminate some of the claims which are properly a part of Group I (composition claims), such as claims 10, 20, 29, 44, 138-144 and 145-152, since these claims recite emulsion vehicles and/or the composition existing as an emulsion. In view of the above, Applicants requests modification and clarification of the present election requirement.

Conclusion

In view of the arguments made herein, Applicants respectfully submit that the outstanding Restriction/Election Requirement is improper and should be withdrawn, or at least amended. If the Examiner believes that a telephone conversation with Applicant's Attorney would be helpful in expediting prosecution of this application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Dated: June 5, 2003

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